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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,948

12/12/2003

Jong Kil

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/735,948	Applicant(s) KIL ET AL.	
	Examiner REX HOLMES	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-16 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-16 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 9-16 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Any negative limitation or exclusionary proviso must have basis in the original disclosure. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. MPEP 2173.05(i). In this case the language “from only a portion of a first ... from only a portion of a second” in claims 1 and 16 is not disclosed in the original disclosure and thus fails to comply with the written description requirement. The specification does not recite that the device uses only a first portion and only a second portion. The mere lack of a description of other signals, in one embodiment does not give proper basis to claim a negative limitation that requires **only** a portion of a signal.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 9-16 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedberg et al (U.S. Pat. 5,740,811 hereinafter “Hedberg”).

4. Referring to claims 1, 2, 15-16 and 26, Hedberg teach a method and apparatus that comprises an implantable cardiac stimulation device having an atrial and ventricular electrode and sensing atrial and ventricular signals. The signals are combined and a surface ECG is obtained in an extracorporeal signal processing device (see column 2, lines 55-67 and column 3, lines 1-5 and column 4, lines 40-49 and figure 1). Hedberg further discloses that the device emulates from individual portions of each signal (e.g. Fig. 4; Col. 5, ll. 30-37). While Hedberg do not explicitly use the term “concatenate” of the atrial and ventricular signals, the Examiner is considering the definition of concatenating to be the joining of two strings or linking together which Hedberg does. Regarding claim 9, Hedberg teach sensing atrial and ventricular signals using unipolar sensing by employing the electrodes in combination with the housing of the device (see column 4, lines 40-49). With regards to claim 10, Hedberg teach a right atrial tip electrode and a right ventricular tip electrode (see figure 1 and column 4, lines 40-42 and lines 52-53). With reference to claim 11, Hedberg teach that local noise is filtered out of the signals (see column 5, lines 27-29 and lines 46-48), and referring to claim 12,

Hedberg teach combining by addition signals received from different electrodes (see column 6, lines 54-57). Regarding claim 13, also teaches using the emulated EKG to adjust parameters controlling the implant (see column 2, lines 13-22). Regarding claim 14, Hedberg teach that the components that generate the synthesized ECG can be completely contained within an implantable unit (see column 2, lines 65-67 and column 3, line 1).

Response to Arguments

5. Applicant's arguments filed 5/9/08 have been fully considered but they are not persuasive. The applicant points out that figures 9-10 and their corresponding description in paragraphs 77-78 disclose emulating a surface EKG, "from only a portion of a first ... from only a portion of a second". Nowhere in the specification or in the pictures does it show that emulated an emulated surface EKG signal having a first portion formed from **only** a portion of a first cardiac signal and a second emulated portion formed from **only** a portion of a second cardiac signal. (emphasis added) In this case the Applicant failed to point out a basis for forming a first portion from **only** a portion of a first cardiac signal and a second emulated portion formed from **only** a portion of a second cardiac signal. (emphasis added) The specification is silent and does not suggest that the emulation is made from **only** a portion of a first and **only** a portion of a second cardiac signal. (emphasis added) For this reason, "only" is not described in the original disclosure, in combination with the other steps or elements in the claim, and it is considered a negative limitation/exclusionary proviso because it precludes other elements/steps. Any claim containing a negative limitation/ exclusionary proviso, which does not have basis

in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. MPEP 2173.05(i).

6. The Applicant further argues that Hedberg does not concatenate the signals. Concatenate taken in its broadest reasonable interpretation means to join or to link together, Hedberg do that by linking and joining together multiple signals to create an emulated surface EKG signal. Further the claim is a comprising claim and does not preclude the use of Adding or using BOTH signals for the first link and BOTH signals for the second link.

7. The Applicant further argues that the system of Hedberg utilize multiple signal to emulate the surface EKGs and thus does not concatenate separate portions of cardiac signal having a first emulated portion formed by a portion of a first cardiac signal and a second emulated portion formed by a portion of a second cardiac signal. The Examiner respectfully disagrees as the Applicant drafted the claim in a comprising format, an open ended claim, and thus the claim does not preclude the use other cardiac signals to create an emulated EKG. Hedberg discloses a system that senses separate cardiac signals and then selectively concatenates the portions to yield an emulated signal (See Figs. 4 and 6-9). Although the system of Hedberg utilizes signals created using multiple signals, there is a portion created from only a portion of a first signal and from only a portion of a second signal (e.g. Col. 5, ll. 30-37).

8. The Applicant argues that the surface ECG shown in figure 4 is actually a surface ECG and not created from the internal signals. The examiner cited figure 4 to show the applicant the different internal signals that can be sensed by the Hedberg system.

Further as noted in the specification of Hedberg, the surface ECG in figure 4 is indeed an actual surface ECG signal and is shown along side the internal sensed signals to show the individual features of the internal signals in comparison to the actual surface ECG. Hedberg shows that the individual features of the signals can be combined to create a emulated signal that is representative of an external ECG (see Figs. 6-9).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762